

REMARKS/ARGUMENTS.

1. CLAIM REJECTIONS: 35 USC §103.

1.1 Maier-Borst *et al* and Wheaton.

Claims 1, 3-7 and 15-17 stand rejected as lacking an inventive step over the combination of Maier-Borst *et al* (GB 2056471 A) and Wheaton [Indust.Eng.Chem., 43, 1088-1093 (1951)].

First, applicants have amended claim 1 to more distinctly define the subject matter of the present invention.

The Examiner states that the person skilled in the art would be motivated to choose bicarbonate from the resin counterions taught by Wheaton in the anion exchanger comprising quaternary ammonium groups of Maier-Borst *et al*, since Wheaton teaches that bicarbonate provides for a "...minimal amount of swelling and thus greater selectivity...".

Applicants respectfully disagree with that analysis. If, following the Examiner's logic, the person skilled in the art were assumed to choose the counterion for the ionic form of the anion exchange resin based on minimizing the swelling characteristics, then Table I (page 1089) of Wheaton teaches that the following 5 resins would all have superior characteristics to bicarbonate:

- (i) iodide;
- (ii) bromide;
- (iii) nitrate;
- (iv) nitrite; and
- (v) chloride.

Hence, applicants contend that the person skilled in the art, if *arguendo* assumed to be seeking to modify Maier-Borst based on resin selectivity as taught by Wheaton, would choose one or more of iodide, bromide, nitrate, nitrite or chloride ahead of bicarbonate. The facts are that Wheaton clearly teaches that 5 other resin counterions would be expected to have superior characteristics to bicarbonate. The motivation for the person skilled in the art stems from an expectation of improved results. It would be entirely illogical to combine Maier-Borst and Wheaton and yet ignore the clear teaching of Wheaton on 5 resins with reported superior selectivity. The Examiner has provided no argumentation to support this illogical choice – demonstrating that the attack is based on an invalid, hindsight approach. The logical combination of Maier-Borst and Wheaton thus teaches away from the presently claimed subject matter.

Present claim 1 is therefore believed to be inventive over the combination of Maier-Borst and Wheaton. By definition, dependent claims 2 to 7 are also believed non-obvious. Claims 8 and 15 are independent claims, which both refer to claim 1 and hence contain all the essential features of claim 1. They, and their associated dependent claims (9-14 and 16-17 respectively) are therefore believed inventive for the same reasons.

The obviousness rejection of present claims 1, 3-7 and 15-17 based on combination of Maier-Borst and Wheaton should therefore be withdrawn.

1.2 Griffiths and Bottcher plus Maier-Borst *et al* and Wheaton.

Claims 1-19 stand rejected as lacking an inventive step over the combination of Griffiths (WO 2003/059397 A2) and Bottcher (US 5,439,863) and further in view of Maier-Borst *et al* and Wheaton.

The Examiner states that the following are obvious:

- (i) to use the microwave activation method of Bottcher in the ^{68}Ga -DOTA-peptide complex formation of Griffiths [paragraph 13];
- (ii) to use the anion exchanger taught by Maier-Borst to separate ^{68}Ga from ^{68}Ge when eluting a radioisotope generator having an aluminum oxide column – to avoid eluting with EDTA and having to destroy a ^{68}Ga -EDTA complex [paragraph 14];
- (iii) that the separation of ^{68}Ga from ^{68}Ge using an anion exchange resin comprising quaternary ammonium groups may comprise bicarbonate as the counterion, since Wheaton teaches that “...provides for a minimal amount of swelling and thus greater selectivity” [paragraph 15].

Objection (i).

Although not explicitly stated, applicants assume that the Examiner's logic is that the subject matter of present claims 1 and 3 to 7 was viewed as obvious over Maier-Worst and Wheaton,

and that the additional features of claims 8 to 14, 18 and 19 could be found in an obvious manner in Griffiths and/or Bottcher.

The objection based on Bottcher is apparently directed at present claim 13 (only), since that is the only claim wherein ^{68}Ga -metal complex formation using microwave activation are essential features.

Applicants first of all point out that the above logic is flawed, since present claims 1 and 3 to 7 are non-obvious over Maier-Worst and Wheaton (*see 1.1 above*). Although Griffiths teaches ^{68}Ga metal complex formation, as acknowledged by the Examiner at 9, Griffiths is silent on anion exchangers using HCO_3^- or containing amine functional groups or based on polystyrene-divinylbenzene. Hence, the combination [Maier-Worst + Wheaton + Griffiths] does not provide all the essential features of present claims 8 to 12, 14, 18 and 19. Similar logic applies to claim 13, since the combination [Maier-Worst + Wheaton + Griffiths + Bottcher] does not provide all the essential features of present claim 13.

Put another way, Griffiths and Bottcher individually or together, cannot remedy the deficiencies of Maier-Worst and Wheaton with respect to present claims 1 and 3 to 7.

Consequently, obviousness rejection (i) should be withdrawn.

Objection (ii).

Although not explicitly stated, applicants assume that the Examiner's logic is that the subject matter of present claim 1 was viewed as obvious over Maier-Worst and Wheaton, and that the additional features of claim 2 can be found in an obvious manner in Maier-Borst.

Applicants first of all point out that the Examiner's logic is flawed, since the subject matter of present claim 1 is non-obvious over Maier-Worst and Wheaton (*see 1.1 above*). Hence, the combination [Maier-Worst + Wheaton + prior art cited by Maier-Worst] does not provide all the essential features of present claim 2.

Secondly, the Examiner refs to page 1 lines 10-18 of Maier-Worst. The prior art ^{68}Ga generator referred to there uses an aluminum oxide column (line 12). Present claim 2 has a titanium dioxide column as an essential feature. That is completely different to aluminum oxide. Hence, for that reason also the combination does not provide all the essential features of present claim 2.

Finally, the Examiner has argued that the obvious combination [Maier-Worst + Wheaton + prior art cited by Maier-Worst] provides $^{68}\text{Ga}/^{68}\text{Ge}$ separation using an aluminum oxide column. That teaches away from the subject matter of present claim 2, and is thus positive evidence in favor of an inventive step for claim 2.

Consequently, obviousness rejection (ii) should also be withdrawn.

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Objection (iii).

This objection apparently reiterates the objection of Maier-Worst + Wheaton (see 1.1 above), and has been dealt with there.

Obviousness rejection (iii) should therefore also be withdrawn.

2. DOUBLE PATENTING.

Claims 1, 2 and 6-14 stand provisionally rejected in this regard over copending US applications 10/552134 and 11/358681.

Applicants submit that a terminal disclaimer will be filed once the present application is indicated to be allowable.

CONCLUSION

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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